



CARDIOVASCULAR SYSTEMS, INC.

K041630

Summary of Safety and Effectiveness

Company Name: Cardiovascular Systems, Inc.
2715 Nevada Avenue North
New Hope (Minneapolis), MN 55427

JAN 31 2005

Contact: Michael J. Kallok, Ph.D.
President and CEO

Phone: (763) 544-1890

Fax: (763) 544-1892

Summary Date: June 10, 2004

Trade Name: Cardiovascular Systems, Inc. Orbital Atherectomy System (CSI OAS) for
Treatment of A-V Shunt Stenosis

Common Name: Peripheral Atherectomy Device

Classification Name: 21 CFR 870.4875, Peripheral Atherectomy Catheter

Predicate Device:

510(k) Number: K970080

Manufacture: Arrow

Trade Name: Arrow-Trerotola PTD

510(k) Number: K901206

Manufacture: Boston Scientific (Acquired from Heart Technology, Inc.)

Trade Name: Rotablator Orbital Atherectomy System - Peripheral Use

510(k) Number: K972357

Manufacture: Boston Scientific

Trade Name: Blue Max[®] 20[™] Balloon Catheter

1.0 Description of Device

The Orbital Atherectomy System (OAS) is intended for use in treatment of artificial arteriovenous dialysis fistula stenosis. An artificial arteriovenous dialysis fistula (A-V shunt) is placed sub-dermal to support kidney dialysis. A consequence of the body's reaction to the foreign material of the A-V shunt is to form clots and neointimal stenosis

of the A-V shunt. The most common location for A-V shunt stenosis is at the shunt to vein anastomosis. It is this region that the Cardiovascular Systems, Inc. (CSI) Orbital Atherectomy System is applied to remove neointimal tissue causing a stenosis in the A-V shunt.

2.0 Intended Use

The Orbital Atherectomy System supports removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).

3.0 Technology

The Orbital Atherectomy System (OAS) provides a method of removing occlusive neointimal tissue. The OAS applies a diamond coated, eccentrically rotating cutting surface to ablate neointimal tissue. The resulting particles of removed neointimal tissue are very small and can be absorbed by the body.

4.0 Conclusions

The OAS is substantially equivalent to the predicate devices. Laboratory and animal data were provided to support the safety of the OAS for use in the treatment of A-V shunt stenosis. No new questions of safety or effectiveness are raised.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2005

Cardiovascular Systems, Inc.
c/o Mr. Gary Syring
Principal Consultant
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K041630

Trade Name: Orbital Atherectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Catheter, Peripheral, Atherectomy
Regulatory Class: Class II
Product Code: MCW
Dated: December 23, 2004
Received: December 27, 2004

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

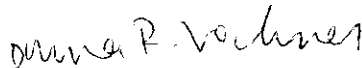
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041630

Device Name: Orbital Atherectomy System for Treatment of A-V Shunt Stenosis

Indications for Use:

The Orbital Atherectomy System supports removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lockner
(Division Sign-Off)
Division of Cardiovascular Devices

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